

## **REMARKS**

Applicants have carefully reviewed the Office Communication of February 28, 2007 and the Office Action of August 11, 2005, in which claims 1-81 are currently pending in the application, claims 9-11, 20, 25-40, 50-52 and 65-81 have been withdrawn from consideration, and claims 1-8, 12-19, 21-24, 41-49 and 53-64 have been rejected. Claims 2 and 41 have been amended with this response. This response is crafted to be fully responsive to the Office Action of August 11, 2005 in light of the Office Communication of February 28, 2007. Favorable consideration is requested.

### ***Information Disclosure Statement***

Applicants bring to the Examiner's attention that Information Disclosure Statements were filed on October 29, 2003 and January 26, 2005, but have not received initialed Form PTO-1449s indicating consideration by the Examiner. Both Information Disclosure Statements can be found in the IFW in PAIR. Applicants request that the Examiner consider the Information Disclosure Statements and return an initialed Form PTO-1449 indicating such consideration of each with the next PTO communication.

### ***Withdrawn Claims***

As a preliminary matter, it is noted that the Office Action states that claims 9-11, 20 and 50-52 have been withdrawn from consideration. Applicants point out that in the Response to Election/Restriction Requirement filed on December 29, 2004, claims 25-40 and 65-81 were also withdrawn from consideration.

### ***Claim Amendments***

Claim 2 has been amended to include a word inadvertently omitted. No new matter has been introduced.

Claim 41 has been amended with this response. This amendment was presented in the response of January 4, 2006, which was considered as not fully responsive. It is therefore not clear that this amendment was entered when presented in that response and is therefore being presented here as if it was not. In any case, applicants respectfully request that the amendment

be considered as properly presented. Support for the amendment can be found, for example, in Figure 15. No new matter has been introduced.

### **Rejections Under 35 U.S.C. § 102**

Claim 1 stands rejected under 35 U.S.C. §102(b) as being anticipated by Kokish et al., U.S. Patent No. 6,485,500 (hereinafter Kokish). Applicants respectfully traverse this rejection. In order for a prior art reference to anticipate a claim, each and every element of the claim must be present in the cited prior art. See M.P.E.P. § 2131.

Claim 1 is a method claim that recites, in part, “deploying the first deployable structure adjacent the treatment site to create movement of the treatment material adjacent the treatment site.” Applicants respectfully submit that Kokish does not appear to disclose at least this portion of claim 1.

Kokish is directed to an emboli protection system that provides one or more inflatable blocking balloons for isolation of a section of a blood vessel to prevent migration of emboli from the section during an interventional procedure, and fluid infusion and evacuation ports for flushing emboli from the isolated section. While Kokish does discuss the introduction of fluid to flush the emboli from the isolated area, there appears to be no teaching or suggestion of deploying a deployable structure adjacent the treatment site to create movement of the treatment material adjacent the treatment site as in claim 1. In Kokish, the movement of the introduced fluid appears to be due to the pressure with which the fluid is introduced, and/or the pressure differential that the fluid creates. (see, for example, Col. 4, lines 13-23). In any event, there appears to be no teaching or suggesting of deploying a deployable structure to create movement of a treatment material adjacent the treatment site.

In fact, in Kokish, it appears as though the balloons or other deployable structures are deployed prior to the introduction of fluids. In other words, the introduction of fluids in Kokish does not occur until after such deployable structures are deployed. (For example, see Col. 4, lines 8-23; Col. 11, lines 27-36; and Col. 16, line 55 through Col. 17, line 17, where Kokish describes the breaking-up of the plaque material in the vessel, followed by the introduction of a fluid to flush the emboli created.) As such, the deployment of the structures in Kokish cannot create movement of the introduced fluid because the fluid has not yet been introduced when the structures are deployed.

As such, Kokish does not teach or suggested each and every element of claim 1. Withdrawal of this rejection is respectfully requested.

Further issues were raised in the Office Communication. Applicants agree with the first two points raised in the Office Communication; claim 1 is not limited to a specific area in a blood vessel but can apply to any treatment site in a blood vessel, and the balloons of Kokish were understood to be the first and second deployable structures. The third point raised also appears to be true, but applicants cannot quite understand why it was raised; when the deployable structures are introduced is not directly pertinent to whether a deployable structure is deployed to create movement of the treatment material. The last point raised, that the invention of claim 1 and Kokish are not able to be differentiated because both Kokish and the present application deploy the structures first and then introduce treatment material. Here, applicants must respectfully disagree. Claim 1 may encompass methods where the first deployable structure is deployed prior to introducing the treatment material. However, if that is the sole operation of the first deployable structure (apart from retraction), claim 1 would not read on that method because that deployment is not a deployment to create movement of the treatment material adjacent the treatment site. An example of a method step that the “deploying the first deployable structure” step of claim 1 would read on can be found in paragraph 57 of the present application: “The more proximal balloon assembly 14 is being inflated (deployed) and deflated (un-deployed) repeatedly adjacent the treatment site 38. Such movement of the proximal balloon assembly 14 causes fluid movement within the vessel, and cause the treatment material 42 to make contact with the treatment site 38.” Such deployment is “deploying the first deployable structure adjacent the treatment site to create movement of the treatment material adjacent the treatment site” as recited in claim 1. Such deployment is not disclosed by Kokish and for at least that reason, applicants respectfully submit that the method of claim 1 is differentiated from the methods disclosed by Kokish and that claim 1 is therefore not anticipated by Kokish.

#### **Rejections Under 35 U.S.C. § 103**

Claims 2-8, 12-19, 21-24, 41-49 and 53-64 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Kokish in view of Tsugita (U.S. Patent No. 6,620,148), and Harrison, et al. (U.S. Patent No. 5,554,119), and further in view of Wright (U.S. Patent No. 5,135,484)

Slepian (U.S. Patent No. 5,328,471), Goodin (U.S. Patent No. 5,397,307), and Bagaoisan et al. (U.S. Patent No. 6,398,773). Applicants respectfully traverse this rejection.

With regard to the rejection, in order for references to render a claim obvious, each and every element of the claim must be present in the cited prior art. See M.P.E.P. § 2143.03. As discussed above, Kokish does not appear to teach or suggest deploying a deployable structure adjacent the treatment site to create movement of the treatment material adjacent the treatment site as in independent claim 1. Further, Kokish does not appear to teach or suggest a “second deployable structure adapted to be deployed adjacent the treatment site to create movement of the treatment material adjacent the treatment site” (emphasis added) as in amended independent claim 41.

In particular, applicants would note in particular that the method of claim 2 is not discussed with any specificity in the Office Action or in the Office Communication. This method, which recites “repeatedly deploying and un-deploying the first deployable structure adjacent the treatment site to create movement of the treatment material adjacent the treatment site,” has elements not even alleged to be present in the cited prior art (nor, by the way, do applicants believe these elements to be present) and for at least this additional reason, applicants submit that this claim is in condition for allowance.

The additional references cited by the Examiner, including Tsugita, Harrison, et al., Wright, Slepian, Goodin, and Bagaoisan et al., do not cure the deficiencies of Kokish. In particular, none of these references appear to teach or suggest deploying a deployable structure adjacent the treatment site to create movement of the treatment material adjacent the treatment site as in independent claim 1, or a second deployable structure adapted to be deployed adjacent the treatment site to create movement of the treatment material adjacent the treatment site as in amended independent claim 41. As such, Applicants respectfully assert that independent claim 41 is allowable over the cited references, and that dependent claims 2-8, 12-19 and 21-24, 42-49 and 53-64 are allowable over the cited references because they depend on either claim 1 or 42, and because they recite additional patentable subject matter.

As an additional matter, on pages 3 and 4 of the Office Action, the Examiner seems to be indicating that the apparatus disclosed in Kokish et al. can be modified with the expandable filters described in Tsugita to render some of the claims obvious (but there is no specific identification of which claims). The applicants respectfully traverse this

combination/modification of Kokish et al. with Tsugita because there is no motivation or suggestion to one or ordinary skill in the art to do so.

For example, Kokish et al. teaches away from the use of filters. The Background section of Kokish et al. includes a discussion of disadvantages associated with the use of filters, indicates a need to overcome these disadvantages, and then proposes to overcome these disadvantages through the use of their system including blocking balloons. (see, Col. 2, lines 14-40; and 56-64). As such, upon the reading of Kokish et al., one of skill in the art would be dissuaded from using filter structures – especially in combination with the apparatus disclosed in Kokish et al.

Additionally, the proposed modification of using a filter within the system of Kokish et al. would change the principle of operation of Kokish et al. (see, M.P.E.P. 2143.01). Kokish et al. discloses an aspiration system for removal of emboli from an isolated section of a blood vessel – the use of a filter rather than the aspiration system would change the entire principle of operation of Kokish et al. regarding the removal of emboli.

For at least these reasons, applicants submit that claims 2-8, 12-19 and 21-24, 41-49, and 53-64 are allowable over the cited references, either alone or in combination. Withdrawal of this rejection is respectfully requested.

Reexamination and reconsideration are respectfully requested. It is respectfully submitted that all pending claims are now in condition for allowance. Issuance of a Notice of Allowance in due course is requested. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

Respectfully submitted,

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By their Attorney,

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